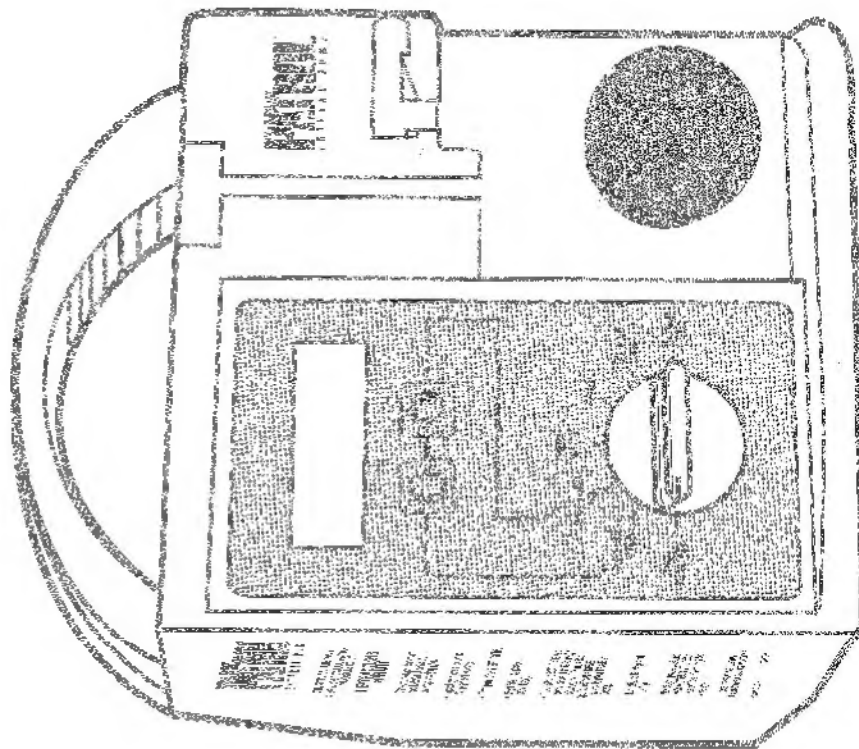


FLEXFLO® **PATROL** ENTERAL PUMP

OPERATING MANUAL

For Enteral Use Only
Not For IV Use



ROSS
 MEDICAL
 NUTRITIONAL
 SYSTEM®

ROSS PRODUCTS DIVISION
 ABBOTT LABORATORIES INC.
 COLUMBUS, OHIO 43215-4724 USA

Pump Characteristics	4
Indications For Use	5
Precautions	5
Panel Displays	6
Control Dial Settings	7 & 8
Pump Sets	9
Instructions For Use	10 & 11
Checking Pump Accuracy	12
Trouble-Shooting	13 & 14
Cleaning	15
Storage	16
Service	16
Specifications	17
Warranty	18

LIMITED WARRANTY PLAN

Ross Products Division of Abbott Laboratories warrants the Flexiflow Patrol® Enteral Pump against defects in material and workmanship for a one (1) year period from date of delivery. This warranty is valid only to the original purchaser and does not extend to any product or part thereof, which has been subjected to accident, alteration, damage, misuse, repair by other than Ross authorized representatives, or has not been operated and maintained in the manner prescribed in the Operating Manual or which at the time of pump failure was being used with pump sets or containers other than Ross pump sets and containers. Examples of damage or misuse include, but are not limited to, pumps that have been dropped, have had fluid spilled into or onto the casing or have been submerged.

In no event shall Ross be liable for any incidental, indirect or consequential damages in conjunction with the purchase or use of the pump, even if advised of the possibility of the same.

Ross reserves the right to repair or replace (at its option) any pump that fails to meet the foregoing warranty.

THE WARRANTIES HEREUNDER ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE.

NOTE:
When repairs on the unit are made under warranty because of faulty material or workmanship within one year from the date of delivery to the customer, the customer will not be billed for parts repaired or replaced. Also, the customer will not be charged for labor involved in connection with the installation of such parts furnished under warranty.

Shipping costs for units returned to Ross, including carriers, shall be paid by the customer. The units should be promptly returned properly packaged. Loss or damage in return shipments to Ross shall be at the customer's risk. Ross authorization should be obtained to return the unit.

PUMP CHARACTERISTICS

The Flexiflo® Pilot® External Pump is a microprocessor (computer) controlled, rotary peristaltic pump that provides for accurate, controlled enteral feeding in a safe, user-friendly system. It has a large, easy-to-read display and simple controls. The Pilot Pump uses a specially designed feeding set, which includes a hour-prevention feature to provide safe, accurate control of enteral feeding.

PRECAUTION: This pump is designed to deliver liquid enteral feeding products only (standard liquid products, infant formulas, or reconstituted powder products that have been thoroughly mixed into solution).

The Flexiflo Pilot Pump offers these features:

1. Alarms for flow-low
2. Flow-rate selection from 1 to 300 mL/hr in 1 mL/hr increments
3. Accuracy to $\pm 1.0\%$ or 50.5 mL/hr, whichever is greater (refer to CHUCKING PUMP ACCURACY, page 12)
4. Dose setting
5. Volume fed accumulation
6. 8-hour battery operation at 125 mL/hr, when fully charged
7. Alarms:
 - **FREE FLO** (free flow)
 - **NO FLO** (no flow)
 - **DOSE FED** (dose fed)
 - **LO BATT** (low battery)
 - **SEL RATE** (invalid rate, select rate)
 - **SEL RUN** (inactive, select run)
 - **E1 to E9** (failed pump software)
8. Programmable **HOLD** timer
9. Lock-out feature
10. System self-check
11. User-friendly operating controls
12. Simple set up
13. Memory - Automatic retention of the following values until turned off:
 - **VOL FED** (volume accumulation)
 - **RATE**
 - **DOSE**

SPECIFICATIONS

Power	
Voltage	100 to 130 VAC, 60 Hz, 1 phase
Power	1.5 watts average
Hose:	200 mL, time-delay type
Line Cord:	disposable, non-reusable (10 feet)
Leakage:	Less than 100 microns per

Mechanical	
Height	8.5 inches
Width	6.5 inches
Depth	4.8 inches
Weight	6.6 lbs

Operational Specifications -- Flow Rates	
Range:	1 - 300 mL/hr
Increment:	1 mL/hr
Accuracy:	$\pm 1.0\%$ or ± 0.5 mL/hr, whichever is greater (refer to CHUCKING PUMP ACCURACY, page 12)
Pressure:	Pumps against 16.4 oz nominal back pressure before NO FLO alarm. Refer to PATROL MAINTENANCE AND REPAIR MANUAL for test procedure.

Battery Operation	
Type:	Rechargeable sealed lead acid
Voltage:	6 V. The pump will fully recharge in a maximum of 4.5 hours while pump is off, or 12 hours if the pump is operating.
Expected life:	When fully charged, 8 hours at 125 mL/hr

Standards:
Designed and manufactured to meet requirements of UL 544.

STORAGE

- The pump should be stored away from excessive heat, cold, or humidity.
- Be sure pump dial is in the OFF position.

SERVICE

- The Patrol® Enteral Pump is designed to be highly reliable. As with any electro-mechanical device, however, minor problems may occur. In the event of a pump malfunction, need for technical assistance or parts, please contact Ross Products Division, Abbott Laboratories.
- OPERATING INSTRUCTION VIDEOTAPE
An instructional videotape in VHS format assists caregivers and medical professionals in learning procedures for operating the FLEXIFLO® Patrol® Enteral Delivery System. This videotape is available for your use through a Ross Representative.

INDICATIONS FOR USE

The Flexiflo® Patrol® Pump can be used for adult and pediatric patients provided the patients can tolerate a feeding range within the pump operational specifications. Those specifications are:

- The flow rate range is 1-300 mL/hr in 1 mL/hr increments.
- The flow rate accuracy is $\pm 0\%$, or ± 0.5 mL/hr, whichever is greater.
- Pumps against 18 psi nominal back pressure before no FLO alarm.

If these specifications are not appropriate for a given patient, the Flexiflo Patrol Pump should not be used.

PRECAUTIONS

- All enteral pumps have the potential to bolus-feed or overdeliver, which is an important consideration in feeding volume-sensitive patients. In these patients, a volume of product no more than four times the hourly feeding rate should be being.

NOTE: Do not rely on free-flow alarm as a criterion for use with volume-sensitive patients.

• NOT FOR IV USE

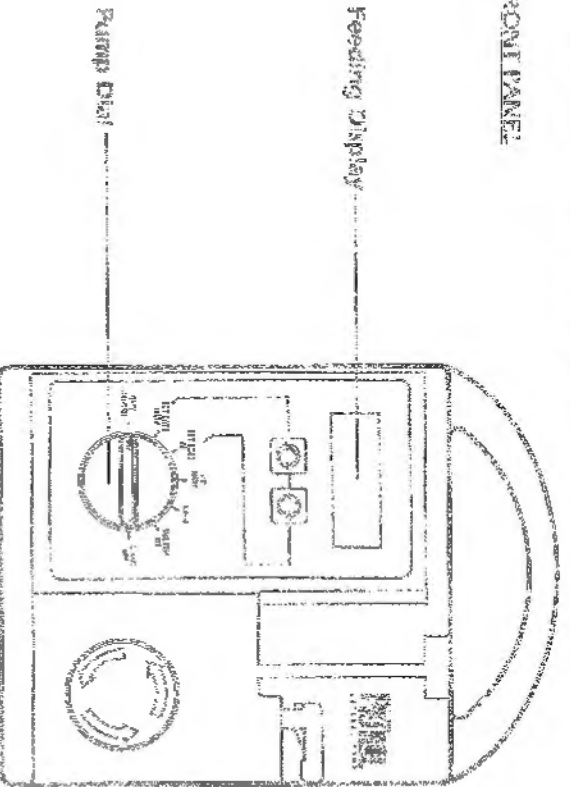
- Confirm proper placement and function of patient's enteral feeding tube (nasogastric, nasojejunal, gastrostomy, etc). Failure to do so may result in vomiting and/or aspiration. Verify the following before initiating feeding:
 1. Only a Flexiflo® Patrol® Pump Set is being used.
 2. Pump set tubing is properly stretched counterclockwise under isoc and blue connector is secured in the pump.
 3. If the feeding set is damaged in any way (eg, broken, cut, torn, parts separated), replace the set immediately.
 4. Flow rate is set at the prescribed mL/hr (refer to page 7 **DIAL SET RATE**).

Pump set and container should be replaced as needed, or at least every 24 hours, to avoid fluid-contamination problems. For single-patient use only.

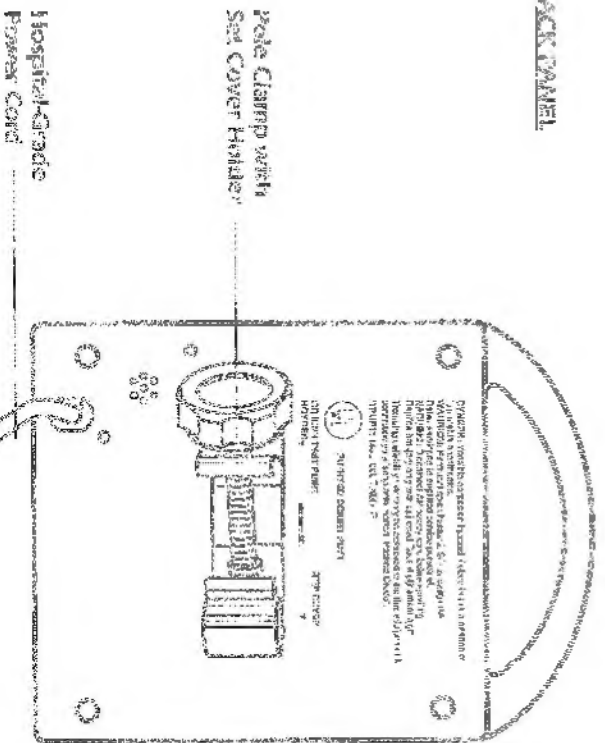
PANEL DISPLAYS

Here is a simple explanation of the panel features. Understanding them is necessary for successful operation of the pump.

FRONT PANEL



BACK PANEL



CLEANING

There are no routine calibration or adjustment procedures required with the Patient Pump. At servicing or adjustments should be referred to qualified technical personnel (refer to Service Manual).

For trouble-free operation, check the pump daily and clean immediately after spills occur.

While cleaning, pump should be turned off and unplugged. Do not spray, submerge, autoclave, heat, steam, ETO or radiation sterilize the pump.

THE PUMP CAN BE CLEANED AS FOLLOWS:

HOUSING

- * Do not spray water or cleaning solution into pump.
- * Clean outside surface only. Use soft cloth and warm, soapy water.
- * For general cleaning, use disinfecting detergent (nonchlorinated) or isopropyl alcohol.
- * For general disinfecting, use 70% concentration isopropyl alcohol.
- * For disinfecting about exposure to AIDS or hepatitis, use 10% concentration of 5, 25% sodium hypochlorite (household bleach). This solution may discolor the pole clamp. After exposure to subcritical, use 70% concentration isopropyl alcohol. These recommendations are not substitutes for official procedures that may differ among institutions.

DROP DETECTOR

- * Clean the drop sensor with a soft brush, soft lint-free cloth or cotton swab and warm, soapy water. Then rinse the drop sensors with clean water and warm water. Be sure no soapy film or residue is left on lenses. Dry thoroughly. **DO NOT CLEAN WITH ALCOHOL.**

ROTOR ASSEMBLY

- * Clean the pump with a soft, lint-free cloth to avoid damaging the surface. Be especially careful with the operator's panel and drop detector area. If necessary, mild warm, soapy water may be used sparingly. Avoid the use of all strong solvents or cleaners as these will damage the pump.

Detach the pump rotor from the pump by loosening the Allen screw. The pump rotor can then be immersed in mild, warm, soapy water or detergent and rinsed under a faucet. Dry excessive moisture from the pump rotor before reassembly.

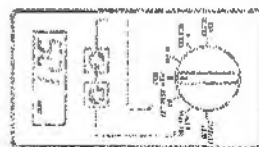
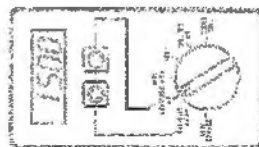
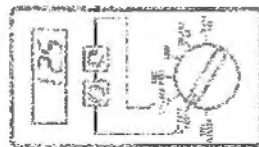
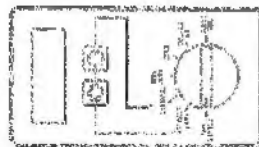
After cleaning, plug the pump into an AC grounded electrical outlet to maintain battery charge.

TROUBLESHOOTING (continued)

CONDITION OR PROBLEM	VISUAL DISPLAY	EXPLANATION OR CORRECTIVE ACTION
HOLD time-out	SEL RUN	Turn dial to RUN.
Electronics error	E1-E9	Remove pump from patient immediately and contact Ross.
Approximately 30 minutes of battery operation remain	LO BATT	<ul style="list-style-type: none"> Turn dial to HOLD, then RUN. Plug power cord into AC outlet for 12 hours, then continue feeding. NOTE: After 30 minutes, pump alarms continuously for one minute and then shuts down.
HOLD countdown	HS	<ul style="list-style-type: none"> Turn dial to HOLD. If desired, program the HOLD timer for 1-90 minutes by depressing the up or down arrow.
Lock-out disables SET RATE, SET DOSE and CLEAR VOL. dial settings	LOC	<ul style="list-style-type: none"> Turn dial to SET RATE. Depress up and down arrows simultaneously to deactivate. Repeat steps to activate.
Display test	8888	All segments should be illuminated.

CONTROL DIAL SETTINGS

DIAL	FUNCTION
OFF/CHARGE	Stops all pump functions. Battery charges in all dial settings when pump is plugged in. The pump will retain current RATE, DOSE and VOL FED values indefinitely unless the pump is unplugged from an AC power source while in the OFF/CHARGE setting.
SET RATE	<p>Allows flow rate to be set (1 to 300 mL/hr in 1-mL/hr increments) by pressing the keypad arrows when the pump is in the SET RATE mode. The up arrow increases the rate. The down arrow decreases the rate.</p> <p>NOTE: The LOC feature may be activated by depressing both arrows simultaneously when the dial is in the SET RATE position. Repeat procedure to deactivate. The SET RATE, SET DOSE, and CLEAR VOL. values cannot be changed while the LOC feature is activated.</p>
SET DOSE	<p>Allows dose to be limited (1 to 9999 mL in 1-mL increments) by pressing the keypad arrows when the pump is in the SET DOSE mode. The up arrow increases the dose. The down arrow decreases the dose.</p> <p>Completion of this dose triggers the dose FED alarm. Refer to dose FED (page 13).</p> <p>NOTE: Pump will operate without a DOSE selected [SET DOSE at 0000].</p>
RUN	<p>Only setting that activates feeding. Visual display shows rate of flow in mL/hr and the dash on the left side of the display scrolls from top to bottom when pump is in RUN mode.</p> <p>NOTE: It is normal for motor movement to be intermittent (e.g. starts, stops, starts, stops, etc) while in the RUN mode. This intermittent movement regulates the rate of flow, conserves battery life and does not affect the accuracy of the pump. The RUN mode should always be verified by the top to bottom scrolling bars on the left side of the display window.</p>

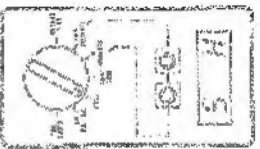


CONTROL, DIAL SETTINGS (continued)

DIAL

FUNCTION

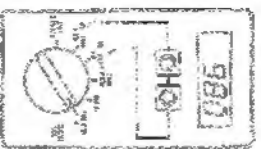
HOLD



Stops pumping action and audio alarms. **HOLD** is used when correcting an alarm condition or whenever pumping action is temporarily interrupted (such as when connecting a new feeding container). If pump is left on **HOLD** for more than 5 minutes, an alarm will sound and the message **SET RUN** (select **RUN**) will be displayed.

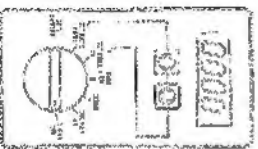
NOTE: The **HOLD** timer may be programmed for a duration of 1–90 minutes (in 1 minute intervals) by depressing the keypad arrows either up or down when the dial is in the **HOLD** position.

VOL FEED



Stops pumping action. The display will show the volume delivered. Pump accumulates volume delivered up to 9999 mL, unless the volume is reset to zero by turning to **CLEAR VOL** (for the pump is unblugged while in the **OFF CHARGE** mode). Upon exceeding the maximum volume allowed on the display, the value turns to zero and a new accumulation begins. This is not accompanied by an alarm.

CLEAR VOL



Stops pumping action and resets the volume fed to zero.

NOTE: The pump will "beep" four times before clearing the volume to alert users that the dial has been turned to **CLEAR VOL**. The user must turn dial away from **CLEAR VOL** (to any other setting) before the fourth beep to avoid an unintentional loss of accumulated volume.

TROUBLE-SHOOTING

The FlexFeeder® or Oral Pump is designed to be highly reliable. As with any electromechanical device, however, problems may occur. Intermittent audio alarms are accompanied by messages on the front panel indicating the cause of the alarm for all alarm conditions. The following tips will help correct problems that may arise:

CONDITION OR PROBLEM	VISUAL DISPLAY	EXPLANATION OR CORRECTIVE ACTION
----------------------	----------------	----------------------------------

Flow has stopped due to occlusion or empty container	NO FLO	<ul style="list-style-type: none"> Turn dial to HOLD. Clear obstruction/check for kinked tubing or empty container. Refill container, if necessary. Be sure sight chamber is not overfilled or covered with a film of product. Turn dial to RUN to start pump.
--	--------	---

Dose complete: VOL FEED; input to the SET DOSE	DOSE FEED	<ul style="list-style-type: none"> Turn dial to HOLD. Turn dial to SET DOSE and depress up arrow to increase dose. OR depress down arrow to zero the dose setting. OR turn dial to CLEAR VOL (after four beeps, volume fed will be cleared). Turn dial to RUN to start pump.
--	-----------	---

Free-flow alarm	FREE FLO	<ul style="list-style-type: none"> Remove from service immediately. Verify pump set is properly installed. Replace set if necessary. Confirm no leaks fall when in HOLD. * Check accuracy per page 12.
-----------------	----------	---

Dial turned to RUN without selecting a rate	SEL RATE	<ul style="list-style-type: none"> * Turn dial to SET RATE. * Enter a rate using the up or down arrow.
---	----------	---

CHECKING PUMP ACCURACY

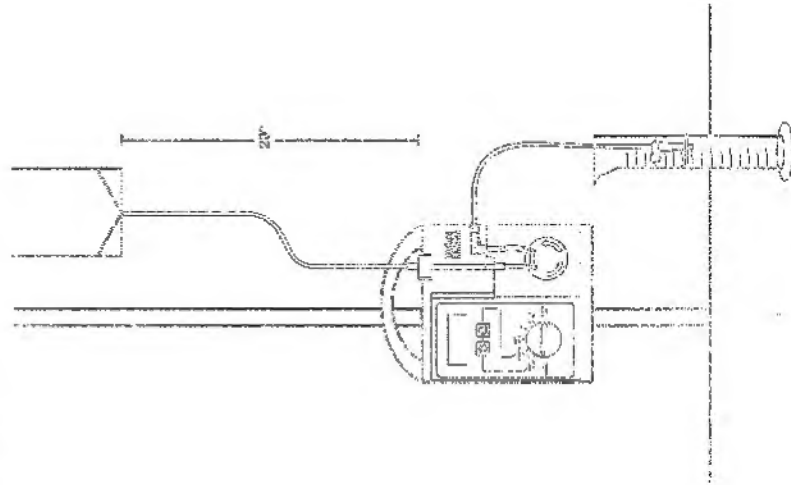
Fluid head height and viscosity are two variables that can affect flow rate. To check flow rate, use the following procedure:

Select a **new pump set for this test**. Be sure to use a graduated cylinder for volume measurement for an enteral container or other uncalibrated vessel. Using Ensure® Complete, Balanced Nutrition™, Osmolite® Isotonic Liquid Nutrition or tap water, fill the feeding container and set up pump according to instructions. Suspend bag to side or behind and 20 inches above pump (see illustration). With the test pump connected to AC power, start the pump and let it run for 15 minutes. Then run fluid into the graduated cylinder for 30 minutes and compare to **SET RATE** on pump.

Amount Expected in Graduated Cylinder
@ 30 minutes

SET RATE	
7½ mL/hr	= 34.2 mL to 41.8 mL
150 mL/hr	= 67.5 mL to 82.5 mL

If amount in graduated cylinder is incorrect based on **SET RATE**, try a new pump set and repeat procedure.

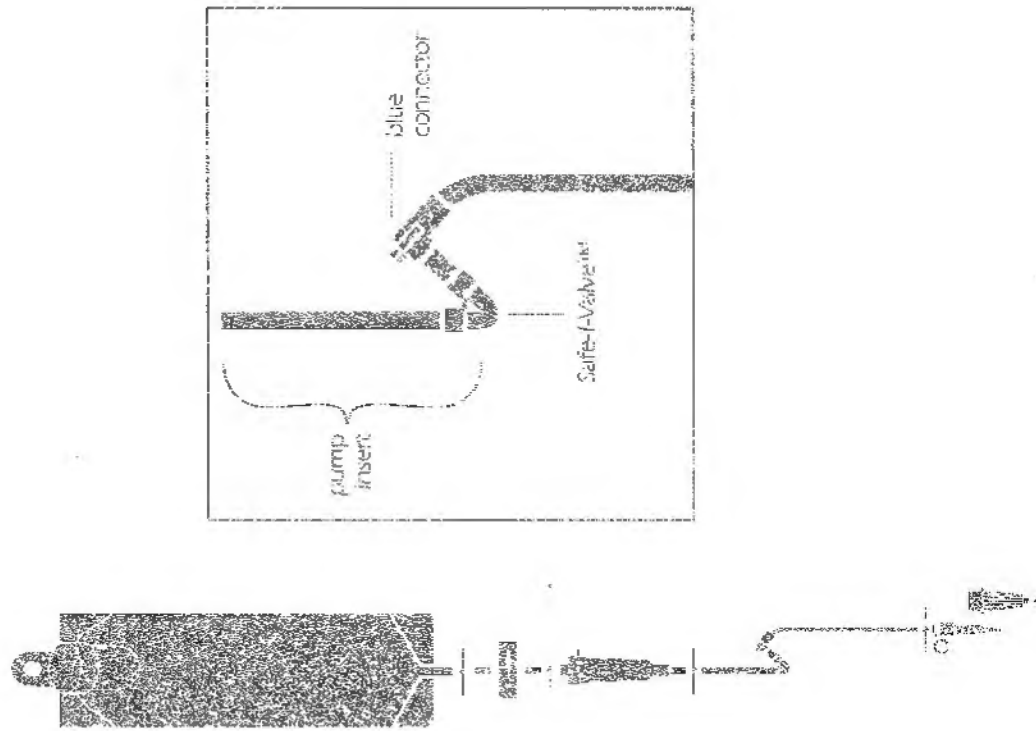


PUMP SETS

The Flexiflo® Pump® Pump offers a wide choice of feeding sets.

PUMP SET EXAMPLE SHOWING

FLEXIFLO® Top-Fill Enteral Nutrition Bag
With Flexiflo® Pump® Pump Set



INSTRUCTIONS FOR USE

Before initial use on battery power and after short dead storage periods, the pump must be plugged into an AC power source for a minimum of 12 hours (pump may be operated during this time). Use AC power whenever possible. Plug in during storage to assure a fully charged battery for emergency.

WARNING: Possible explosion hazard if used in the presence of flammable anesthetics.

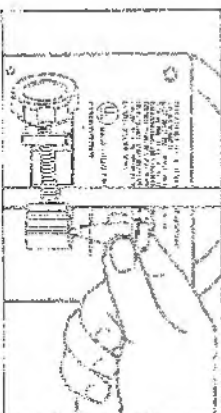
TO ASSEMBLE:

1. Attach pump to stand using pole clamp. Plug in cord if power is available. If using battery power, do not let battery run down. When the low battery message (LCD will appear), the battery has approximately 30 minutes of energy left for pump operation.

2. Complete self-adhesive delivery label and affix to bag.*

3. Attach the Pellicore Pump Set securely onto a filled central must don container. If it is not pre-attached. Suspend container 20 inches above and to the side or behind pump.

4. Place sight chamber into stop detector and seat in place before priming.



5. Remove cover from adapter and discard or place into set cover holder on the pump pole clamp.

*If product is not filled in back, it is someone to that side starts before unspooling. Make sure the clamp is open for setup.

TO PRIME SET:

6. With one hand on the blue connector of the pump set, gently pull until fluid flows.

7. Completely prime the set by allowing fluid to expel air from the tubing.

8. Let fluid slowly enter sight chamber to fill line (1/4 full). NOTE: If sight chamber is filled above the line after priming (over-filled), invert container, holding all tubing above sight chamber and connector with one hand on the sight chamber and the other hand on the blue connector, gently pull until fluid drains from tubing. Suspend container and reprime.

9. Grasp the blue connector on the pump insert. Loop the pump insert under the rotor (counter clockwise).

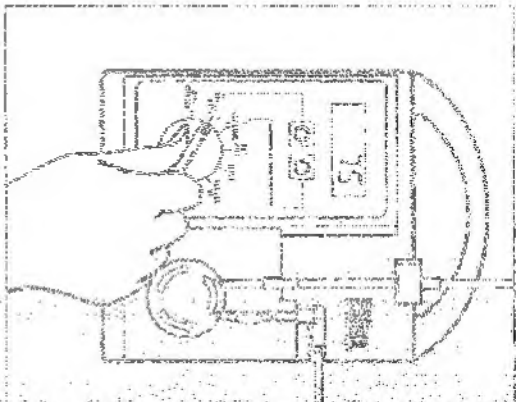
10. Gently pull up and then seat the blue connector in the slot above the rotor.

11. Confirm proper placement and function of central feeding tube.

12. Attach feeding set adapter to central feeding tube.

NOTE: If adapter is used with cover in place, ensure that set is connected away to an external feeding tube (eg. needle catheter, jejunostomy).

INSTRUCTIONS FOR USE (continued)



TO START PUMP:

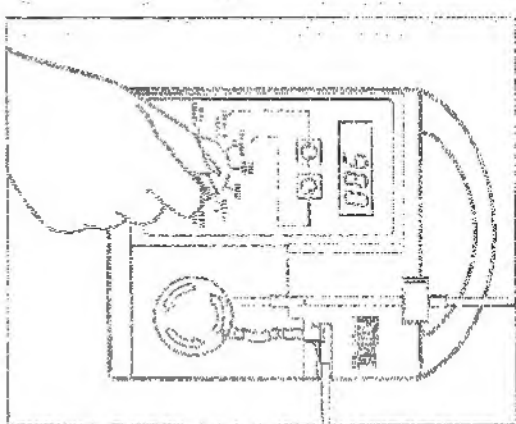
13. Turn pump dial to SET RATE. Pump will initiate system self-check procedure.

14. Select flow rate from 1 to 300 mL/hr by pressing the arrows and observing the entry on the display. Holding down an arrow will set the number to stay. Never use sharp objects such as pens, pencils, fingernails or paper clips to depress the keypad arrows.

15. If desired, turn dial to SET DOSE and select dose by pressing the arrows.

NOTE: Pump will operate without a DOSE selection (SET DOSE etc.) (N/A)

16. Turn dial to RUN to start feeding.



17. To see feeding volume delivered, turn dial to VOL. DEL.

18. To clear the volume delivered, turn dial to CLEAR VOL. (This occurs after four beeps.)

19. When feeding is complete, turn pump dial to OFF.

NOTE: If alarm sounds, turn pump dial to WOULD. Current alarm condition indicated by visual display. Then turn dial to RUN to restart feeding. (For explanation of alarms, see pages 13 and 14.)

PRECAUTION: The pump set and container should be replaced as needed, or at least every 24 hours, to avoid fluid-contaminant problems. For single patient use only. Do not store for prolonged periods at extreme temperatures.